PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Carl D. Wahlstrand, Robert M. Skime, Ruchika Singhal and Darren A. Janzig	Confirmation No.	4796
Serial No.:	10/730,878		
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Group Art Unit:	3762		
Docket No.:	1023-334US01		
Title:	LEAD CONNECTION MODULE OF A MODULAR IMPLANTABLE MEDICAL DEVICE		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on September 14, 2009.

By: _____
Name: Patricia Cygan

BRIEF ON APPEAL

Board of Patent Appeals and Interferences
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

This is an Appeal Brief in support of an appeal from the final Office Action mailed April 1, 2009, which finally rejected claims 1–10, 12–15, and 19–21, and the Advisory Action mailed July 9, 2009, which affirmed the rejection of those claims. The Notice of Appeal was filed July 21, 2009. The period for filing this Brief runs through September 21, 2009.

Please charge Deposit Account No. 50-1778 the amount of $540.00 for submission of this Appeal Brief, as required by 37 C.F.R. § 41.37(a)(2) for a large entity. Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

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REAL PARTY OF INTEREST

The Real Party of Interest is Medtronic, Inc., of Minneapolis, Minnesota.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 1–10, 12–15, and 19–21 are pending and are the subject of this Appeal. Claims 1–10, 12–15, and 19–21 are set forth in the attached Claims Appendix. The originally filed application included claims 1–14. Claims 15–18 were added in an Amendment filed October 18, 2006; claims 19 and 20 were added in an Amendment filed May 21, 2007; and claim 21 was added in an Amendment filed January 23, 2009. Originally filed claim 11 was canceled in an Amendment filed April 11, 2008 and claims 16–18 were canceled in an Amendment filed January 23, 2009.

Claims 1–5, 8–10, 12, 13, 15, and 19–21 stand rejected under 35 U.S.C. § 102(a/e) as being unpatentable over Berrang et al. (U.S. Patent No. 6,358,281 B1, hereinafter "Berrang"), or in the alternative, as being unpatentable under 35 U.S.C. § 103(a) over Berrang in view of Correas (U.S. Patent No. 6,112,120). Claims 6, 7, and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang in view of Correas.

STATUS OF AMENDMENTS

Appellant submitted an Amendment on June 18, 2009 in response to the final Office Action dated April 1, 2009. In the Amendment dated June 18, 2009, Applicant amended the specification. The Advisory Action dated July 9, 209 indicates that the amendment to the specification was entered.

Appellant has not submitted any claim amendments subsequent to the issuance of the final Office Action dated June 18, 2009. The pending claims are those presented in the Amendment and Response to Restriction Requirement filed on January 23, 2009.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites an implantable medical device[1] comprising at least two interconnected modules[2] and an overmold.[3] Each of the interconnected modules comprises a respective one of at least two housings to house the respective modules.[4] The overmold at least partially encapsulates each of the housings[5] and is at least partially flexible[6] to allow relative motion between the modules.[7] The overmold comprises a lead connection module[8] configured to accept an external lead.[9] The external lead is separable from the lead connection module.[10] The lead connection module comprises a feed-through wire that electrically couples to the external lead.[11]

Independent claim 9 recites an overmold[12] for a modular implantable medical device[13] that includes a plurality of modules.[14] Each of the modules comprises a respective housing to

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[1] *See, e.g.*, Appellant's originally filed application at FIGS. 1A and 1B, ref. num. 101; FIG. 2, ref. num. 201; FIGS. 3A and 3B, ref. num. 301; FIGS 4A–4F, ref. num. 401; FIGS. 5A–5C, ref num. 501; FIGS. 6A and 6B, ref. num 601; FIGS. 7A and 7B, ref. num. 701; FIGS. 8A and 8B, ref. num 801; page 4, lines 19–21; page 10, lines 20–23; and page 13, lines 21–25.

[2] *See, e.g., id.* at FIG. 2, ref. nums. 210, 211; FIGS 4A–4F, ref. nums. 410, 411; FIG. 5A, ref. nums. 510, 511; FIGS. 7A and 7B, ref. nums. 710, 711; page 4, lines 3–5; page 7, lines 20–21; and page 8, lines 23–30.

[3] *See, e.g., id.* at FIG. 1B, ref. num. 106; FIG. 2, ref. num. 214; FIGS. 3A and 3B, ref. num. 302; FIGS. 5A and 5B, ref. num. 522; FIGS. 7A and 7B, ref. num. 722; FIGS. 8A and 8B, ref. num. 822; page 4, lines 19–21; page 8, lines 7–22; page 11, lines 10 and 11; page 13, lines 23 and 24; and page 14, lines 10–12.

[4] *See, e.g., id.* at page 4, lines 19–21; page 8, lines 4–7; page 8, lines 26–28; and page 10, lines 22 and 23.

[5] *See, e.g., id.* at FIG. 1B, ref. nums. 103, 104, 105, and 106; FIG. 2, ref. nums. 210, 211, 212, and 214; FIG. 4A, ref. num. 410, 411, and 413; page 4, lines 19–21; page 8, lines 12–22; page 8, lines 26–28; page 10, lines 22–28; page 11, lines 15–17; and page 13, lines 23–25;

[6] *See, e.g., id.* at page 8, lines 18–22; and page 11, lines 15–20.

[7] *See, e.g.*, paragraph [0033] of Appellant's disclosure as amended in the Amendment filed on April 11, 2008.

[8] Appellant's originally filed application at FIG. 2, ref. nums. 213A and 213B; FIGS. 3A and 3B, ref. nums. 303A and 303B; FIGS. 4A–4F, ref. num. 415A, 415B; FIGS. 6A and 6B, ref. num. 613; FIGS. 7A and 7B, ref. num. 713; FIGS. 8A and 8B, ref. num. 813; page 4, lines 21–23; page 4, lines 26–29; page 9, lines 1–7; page 10, lines 1–3; page 13, lines 7–10; page 15, lines 7–9.

[9] *See, e.g., id.* at FIG. 4A, ref. nums. 402A, 402B; FIG. 6A, ref. num. 643; page 4, lines 21–23; page 4, lines 26–29; page 9, lines 1–7; page 10, lines 14–17; page 13, lines 7–10; and page 15, lines 7–9.

[10] *See, e.g., id.* at FIGS. 6A and 6B, ref. nums. 613 and 643; FIGS. 8A and 8B, ref. nums. 813 and 843; page 9, lines 4–5; page 13, lines 7–10; page. 13, lines 29–30; page 15, lines 6–24; and Applicant's disclosure at paragraph [0051[as amended in the Amendment filed on October 2, 2007.

[11] *See, e.g., id.* at FIG. 8B, ref. num. 846; FIGS. 9A and 9B, ref. num. 946; page 15, lines 13–15; page 15, lines 26–31.

[12] *See, e.g., id.* at FIG. 1B, ref. num. 106; FIG. 2, ref. num. 214; FIGS. 3A and 3B, ref. num. 302; FIGS. 5A and 5B, ref. num. 522; FIGS. 7A and 7B, ref. num. 722; FIGS. 8A and 8B, ref. num. 822; page 4, lines 19–21; page 8, lines 7–22; page 11, lines 10 and 11; page 13, lines 23 and 24; and page 14, lines 10–12.

[13] *See, e.g.*, Appellant's originally filed application at FIGS. 1A and 1B, ref. num. 101; FIG. 2, ref. num. 201; FIGS. 3A and 3B, ref. num. 301; FIGS 4A–4F, ref. num. 401; FIGS. 5A–5C, ref num. 501; FIGS. 6A and 6B, ref. num 601; FIGS. 7A and 7B, ref. num. 701; FIGS. 8A and 8B, ref. num 801; page 4, lines 19–21; page 10, lines 20–23; and page 13, lines 21–25.

[14] *See, e.g., id.* at FIG. 2, ref. nums. 210, 211; FIGS 4A–4F, ref. nums. 410, 411; FIG. 5A, ref. nums. 510, 511; FIGS. 7A and 7B, ref. nums. 710, 711; page 4, lines 3–5; page 7, lines 20–21; and page 8, lines 23–30.

house the respective module.[15] The overmold comprises a first material configured to hold at least part of the housing of one of the modules,[16] a second material coupled to the first material,[17] and a lead connection module[18] configured to accept an external lead.[19] At least one of the first or second materials is at least partially flexible[20] to allow relative motion between the modules.[21] The lead connection module is embedded within the overmold[22] and comprises a feed-through wire[23] that electrically couples to the external lead.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following grounds of rejection to be reviewed on appeal:

(1) The first ground of rejection to be reviewed on appeal is the rejection of claims 1–5, 8–10, 12, 13, 15, and 19–21 under 35 U.S.C. § 102(a/e) as being unpatentable over Berrang, or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Berrang in view of Correas.

(2) The second ground of rejection to be reviewed on appeal is the rejection of claims 6, 7, and 14 under 35 U.S.C. § 103(a) as being unpatentable over Berrang in view of Correas.

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[15] *See, e.g., id.* at page 4, lines 19–21; page 8, lines 4–7; page 8, lines 26–28; and page 10, lines 22 and 23.
[16] *See, e.g., id.* at FIG. 5B, ref. num. 531; FIG. 8A, ref. num. 831; page 4, lines 26–29; page 11, lines 10–17; page 11, lines 26–27; and page 14, lines 10–12.
[17] *See, e.g., id.* at FIG. 5B, ref. num. 532; FIG. 8A, ref. num. 832; at page 4, lines 26–29; page 11, lines 10–17; page 11, lines 26–27; and page 14, lines 10–12.
[18] *See, e.g., id.* at FIG. 2, ref. nums. 213A and 213B; FIGS. 3A and 3B, ref. nums. 303A and 303B; FIGS. 4A–4F, ref. num. 415A, 415B; FIGS. 6A and 6B, ref. num. 613; FIGS. 7A and 7B, ref. num. 713; FIGS. 8A and 8B, ref. num. 813; page 4, lines 21–23; page 4, lines 26–29; page 9, lines 1–7; page 10, lines 1–3; page 13, lines 7–10; page 15, lines 7–9.
[19] *See, e.g., id.* at FIG. 4A, ref. nums. 402A, 402B; FIG. 6A, ref. num. 643; page 4, lines 21–23; page 4, lines 26–29; page 9, lines 1–7; page 10, lines 14–17; page 13, lines 7–10; and page 15, lines 7–9.
[20] *See, e.g., id.* at page 8, lines 18–22; page 11, lines 15–20; page 12, lines 14–15;
[21] *See, e.g.*, paragraph [0033] of Appellant's disclosure as amended in Amendment filed April 11, 2008.
[22] *See, e.g.*, Appellant's originally filed application at FIGS. 3A and 3B, ref. nums. 302, 303A, and 303B; FIGS. 6A and 6B, ref. nums. 622 and 613; page 4, lines 26–29; page 10, lines 1–3; and page 13, lines 6–7.
[23] *Id.* at FIG. 8B, ref. num. 846; FIGS. 9A and 9B, ref. num. 946; page 15, lines 13–15; page 15, lines 26–31.

ARGUMENT

Appellant respectfully traverses the current rejections of claims 1–10, 12–15, and 19–21 advanced in the Office Action dated June 8, 2009. For at least the reasons presented below, the Examiner has failed to establish a *prima facie* case of anticipation or obviousness with respect to Appellant's claims 1–10, 12–15, and 19–21. Accordingly, Appellant respectfully requests reversal by the Board of Patent Appeals based on the arguments below. For each ground of rejection, Appellant respectfully requests separate review of each set of claims argued under separate headings.

REJECTION UNDER 35 U.S.C. § 102(A/E) OVER BERRANG OR, IN THE ALTERNATIVE, UNDER 35 U.S.C. § 103(A) OVER BERRANG IN VIEW OF CORREAS

Claims 1–5, 8–10, 12, 13, 15, and 19–21 stand rejected under 35 U.S.C. § 102(a/e) as being unpatentable over Berrang, or, in the alternative, under 35 U.S.C. § 103(a) over Berrang in view of Correas. As discussed in further detail below, neither Berrang nor Berrang in view of Correas discloses or suggests each and every element of Appellant's claims. Thus, the rejection of the claims as being anticipated by Berrang or obvious over Berrang in view of Correas was improper and should be reversed.

CLAIMS 1–5, 8–10, 12, 13, 15, 20, AND 21

In support of the rejection of independent claim 1 under 35 U.S.C. § 102(a/e) over Berrang, the Examiner erroneously characterized a battery 18 and electronics 21 as interconnected modules, a junction 16 as an external lead, a bridge 6 as a lead connection module, and "the disclosed gold and titanium, platinum, silicone, and/or any combination of these" as an overmold.[24]

Independent claim 1 requires, *inter alia*, an overmold that comprises a lead connection module configured to accept an external lead, where the external lead is separable from the lead connection module. The Examiner acknowledged that "Berrang does not expressly disclose that the lead (16) is 'separable from the lead connection module [as required by claim 1],'" but

[24] Advisory Action dated June 8, 2009 at page 4, item 7.

asserted that "the lead is constructed of platinum and an inert polymer (col. 11, lines 3-27), which is inherently 'separable from the lead connection module' by use of, e.g., wire cutters."[25]

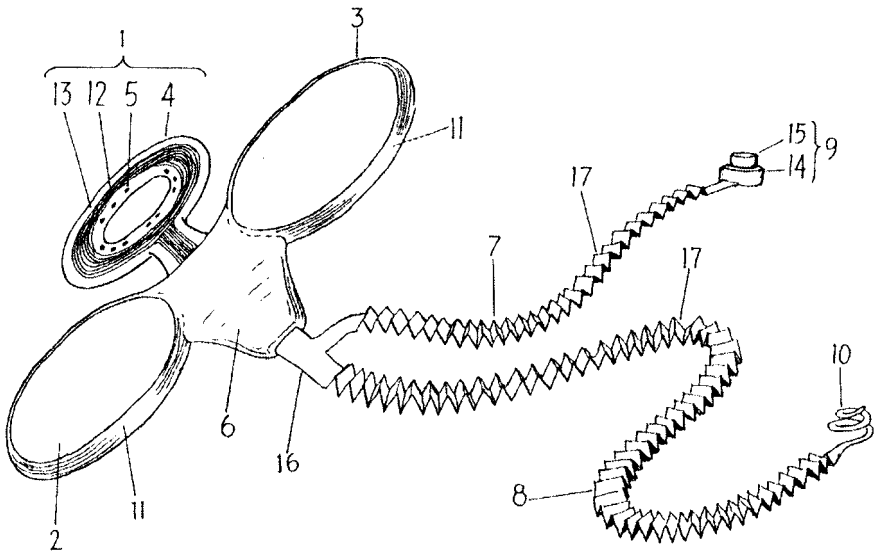

FIG. 1

Berrang does not provide any support for the Examiner's assertion that the junction 16 (characterized by the Examiner as an external lead[26]) of the Berrang device is inherently separable from the bridge 6 (characterized by the Examiner as the lead connection module[27]) by any means, including wire cutters. The Examiner's suggestion of using wire cutters to cut the junction 16 (shown in FIG. 1 of Berrang, reproduced above) of Berrang would ultimately fail to separate the junction 16 from the bridge 6 (also shown in FIG. 1 of Berrang). The use of wire cutters would instead result in maintenance of the proximal portion of the junction (on the proximal side of the cut) within the bridge 6 and severance of only the distal portion of the junction 16 (on the distal side of the cut) from the bridge 6. Thus, the junction 16 would be cut into two pieces upon the application of the wire cutters, whereby one of the pieces would remain within the bridge 6. Therefore, the Examiner's proposed use of wire cutters to cut the junction 16 does not demonstrate that the junction 16 is inherently separable from the bridge 6.

Moreover, the Examiner's proposed use of wire cutters to cut the junction 16 would render the device of Berrang dysfunctional by severing the connection between the electrode

[25] *Id.*
[26] *Id.*
[27] *Id.*

array 10 and the microphone 9 and the remainder of the Berrang device. Indeed, Berrang fails to provide any indication that the junction 16 can be removed from the bridge 6 and replaced, or that the device may operate as intended with a junction 16 that is cut into two separate portions. If a proposed modification would render the Berrang device unsatisfactory for its intended purpose, there is no suggestion or modification to make the proposed modification.[28] For at least these reasons, Berrang fails to disclose or suggest that the junction 16 is inherently separable from the bridge 6 of Berrang, as asserted by the Examiner, and Berrang fails to anticipate Appellant's independent claim 1.

The Examiner provided an alternative rejection of claim 1, and asserted that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Berrang's invention [in view of Correas] by providing a lead that is manually separable and re-attachable to a lead connection module to provide the predictable result of allowing convenient immobilization of a lead on a generator by a surgeon without risk of inopportune disconnection."[29] The Examiner's assertion of obviousness lacks a rational underpinning, and, therefore, is insufficient to support the conclusion of obviousness.[30]

The cited art fails to provide any basis for the rationale that the Berrang device allows for a "risk of inopportune disconnection" of a lead, as asserted by the Examiner. As discussed above, Berrang fails to disclose a device that is configured to accept an external lead that is separable from a lead connection module, as required by independent claim 1. Based on the Berrang reference, the junction 16 (characterized as a "lead" by the Examiner) of the Berrang device is not separable from the bridge 6 (characterized as a "lead connection module" by the Examiner). Thus, it appears that the Berrang device does not necessarily have any more of a "risk of inopportune disconnection" than the Correas device. As a result, the Examiner's proposed rationale for modifying Berrang in view of Correas lacks a rational underpinning.

In the Response to Arguments provided in the Advisory Action dated June 8, 2009, the Examiner stated that:

> Applicant's position appears to be that avoiding a "risk of inopportune disconnection" is not a rational basis for combining Berrang and Correas because Berrang's device does not allow for a "risk of inopportune disconnection," and thus an artisan of ordinary skill would not be motivated to look to Correas to cure a deficiency that does not exist.

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[28] *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).
[29] Advisory Action dated June 8, 2009 at page 5, item 7.
[30] *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

> However, the basis is not merely to avoid inopportune disconnection, but to allow convenient immobilization of a lead on a generator by a surgeon without risk of inopportune disconnection. In other words, this modification allows a surgeon to implant a lead, and then immobilize it on the generator without risk of later disconnection from either the generator or the implantation site, as is notorious in the electrical stimulator arts.[31]

Appellant disagrees with the Examiner's assertion that Correas discloses "allow[ing] a surgeon to implant a lead, and then immobiliz[ing] it on the generator without risk of later disconnection from either the generator or the implantation site." Correas fails to disclose these steps, much less these steps in this particular order.

In actuality, Correas merely states that "the mechanism of the present invention allows . . . to insure an excellent mechanical immobilisation of the probe on the generator, by avoiding therefore all risk of an inopportune disconnection."[32] Disclosure of immobilization of the probe on the generator by Correas indicates that the probe is connected to the generator and is not mobile. To the extent Correas discloses implantation of a lead and immobilization on a generator without risk of later disconnection from the generator or the implantation site, Berrang discloses the same. The junction 16 of the Berrang device is already immobilized, given that the junction of Berrang is secured within the bridge 6 of Berrang. Thus, a person of ordinary skill in the art would have had no rational reason to modify the device of Berrang in view of Correas in order to "allow a surgeon to implant a lead, and then immobilize it on the generator," as asserted by the Examiner.

Appellant respectfully disagrees that the bridge 6 disclosed by Berrang is a lead connection module that includes a feed-through wire that electrically couples to the external lead, as required by Appellant's independent claim 1. The Examiner asserted that the bridge 6 inherently includes at least one feed-through wire that connects the junction 16 to the power source and control electronics housed within the battery 18 and electronics 21.[33] However, Berrang does not disclose or even suggest that the junction 16 is connected to the battery 8 or the electronics 21. Rather, Berrang merely states that the junction 16 is where the cables 7 and 8 merge.[34] Berrang does not disclose that the cables 7, 8 electrically connect to the junction 16, such that the junction 16 (i.e., the "lead" according to the Examiner) would have a reason to

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[31] Advisory Action dated June 8, 2009 at page 8, item 18.
[32] Correas at column 1, lines 63–66.
[33] Advisory Action dated June 8, 2009 at page 4, item 7.
[34] Berrang at column 11, lines 1–3 .

electrically connect to any alleged feed-through wires in the bridge 6. Indeed, nothing in Berrang suggests that separate feed-through wires that electrically couple to the junction 16 are disposed within the bridge 6.

The Examiner relied on an improper finding of an inherent disclosure in Berrang to support the assertion that the bridge 6 of Berrang inherently includes at least one feed-through wire that connects the junction 16 to the battery 18 and electronics 21.[35] The fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that result or characteristic.[36] The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.[37] No reasonable support has been provided for the determination that the bridge 6 necessarily includes a feed-through wire that electrically connects to the junction 16.

As an initial matter, Appellant notes that Berrang does not disclose that the junction 16 includes an electrical component that can even electrically connect to a feed-through wire. While Berrang discloses that cables 7, 8, which include wires, merge in the junction 16, Berrang does not disclose or suggest that the cables 7, 8 electrically connect to the junction 16, which then electrically connects to a feed-through wire in the bridge. Based on the Berrang disclosure, it is possible that the cables 7, 8 merely extend through the junction 16 and bridge 6 in order to directly electrically couple to the battery 18 and electronics 21 (the "interconnected modules" according to the Examiner), rather than the terminating in the junction 16 and the junction 16 electrically connecting to feed-through wires in the bridge 6 in order to connect the cables 7, 8 to the battery 18 and electronics 21.

Berrang also discloses that that the underside of each ceramic substrate 24, 25, which the Office Action characterized as being a "housing" for different modules,[38] contain "a plurality of electrically insulated electrical lead-throughs."[39] Accordingly, the Berrang device does not necessarily include a separate lead connection module that includes a feed-through wire, and the cables 7, 8 that extend through the junction 16 may directly couple to the battery 18 and

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[35] Advisory Action dated June 8, 2009 at page 4, item 7.
[36] *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ.2d 1955, 1957 (Fed. Cir. 1993); MPEP 2112.
[37] *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112.
[38] Advisory Action dated June 8, 2009 at page 4, item 7.
[39] Berrang at column 11, lines 48–50.

electronics 21, which the Examiner characterized as "modules," via the electrical lead-throughs in the ceramic substrates 24, 25.

Berrang also fails to disclose or suggest at least two interconnected modules that each comprise a respective housing to house the respective module, and an overmold that at least partially encapsulates each of the housings, as required by Appellant's independent claim 1. In support of the rejection of independent claim 1, the Examiner characterized the battery 18 and electronics 21 shown in FIGS. 2 and 3 of Berrang as two modules each having a housing encapsulated by an overmold.[40] The Examiner further asserted that the ceramic substrates 24, 25 and the snap domes 20, 23 define a housing for the battery 18 and electronics 21, or, alternatively, the support disc 33 houses the electronics 21 and the battery inherently comprises its own housing.[41]

Neither the support disc 33 nor the ceramic substrate 25 and the snap dome 23 house the electronics 21. Rather, the support disc 33 merely provides a mounting surface for a piezoceramics actuator 22. Berrang describes a piezoceramic actuator 22 that is preferably mounted to a flexible support disc 33.[42] The snap dome 23 may be pushed to cause the piezoceramic actuator 22 on the flexible support disc 33 to slightly bend thereby creating a voltage pulse sufficient to activate the electronics.[43] The support disc 33 does not house electronics 21 and, rather, provides a mounting surface for piezoceramics actuator 22. Further, as illustrated in FIG. 2, the support disc 33 is located proximate to one edge of electronics 21 but not the other surfaces of electronics 21. Therefore, the support disc 33 does not in any way house electronics 21.

Similarly, the ceramic substrate 25 merely provides a mounting surface for the electronics 21 and does not in any way house the electronics 21. Berrang does not describe the relationship between the ceramic substrate 25 and the snap dome 23, and does not disclose or suggest that the ceramic substrate 25 and snap dome 23 define a housing that houses the electronics 21. Independent claim 1 specifies that each of the modules comprises a housing to house the respective module, rather than merely being a component of the module. In contrast, the ceramic substrate 25 and snap dome 23 in Berrang are merely components of a housing

[40] Advisory Action dated June 8, 2009 at page 4, item 7.
[41] *Id.*
[42] Berrang at column 12, lines 32–35.
[43] *Id.* at column 12, lines 35–42.

section 3, rather than housings for the electronic components 21. For at least these reasons, Berrang fails to disclose or suggest modules including respective housings, and, accordingly, fails to disclose or suggest the requirements of independent claim 1.

Berrang clearly and repeatedly describes its device as having a single housing ("the housing") comprising two sections.[44] At no time does Berrang teach or even suggest that the battery 18 and electronics 21 are interconnected modules that each comprise a respective housing to house the respective module in addition to an overmold that at least partially encapsulates the housings, as recited by Applicant's independent claim 1.

The Examiner found that column 11, line 55 to column 12, line 25 of Berrang discloses that an overmold encapsulates each of the "housings" of the battery 18 and electronic component 21.[45] The Examiner has misinterpreted the scope and content of Berrang. At the cited portions of Berrang, Berrang discloses that epoxy surfaces 28 and 31 are covered with a gold layer, which is designed to bond directly to the outside edge of the ceramic substrates 24 and 25, thus creating a sealed, hermetic covering over the components mounted onto each of the ceramic substrates 24 and 25. FIG. 2 of Berrang illustrates a gold foil 27 surrounding the entire Berrang device. This layer of gold is not an overmold, as asserted by the Examiner. Instead, the gold layer forms a single housing for the housing sections 2 and 3, where the housing section 2 includes the battery 18 and the housing section 3 includes the electronic components 21 (the "modules" according to the Examiner).[46]

For at least these reasons, the rejection of independent claim 1 under 35 U.S.C. § 102(a/e) over Berrang, or, in the alternative, under 35 U.S.C. § 103(a) over Berrang in view of Correas was improper and should be reversed. Claims 2–5, 8, 15, and 21 depend from claim 1. For at least this reason, the rejection of claims 2–5, 8, and 21 was also improper. Appellant respectfully requests reversal of the rejection of claims 1–5, 8, 15, and 21 under 35 U.S.C. § 102(a/e) over Berrang, or, in the alternative, under 35 U.S.C. § 103(a) over Berrang in view of Correas.

Independent claim 9 also requires, *inter alia*, an overmold that comprises a first material configured to hold at least part of a housing of one of the modules of a modular implantable medical device, a second material coupled to the first material, where at least one of the first or second materials is at least partially flexible to allow relative motion between the modules, and a

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[44] *Id.* at column 3, line 25 to column 4, line 4 and column 9, lines 51–62.
[45] Advisory Action dated June 8, 2009 at page 4, item 7.
[46] *See* Berrang at column 9, lines 58–62 and column 3, lines 32–35.

lead connection module configured to accept an external lead, where the external lead is separable from the lead connection module, the lead connection module being embedded within the overmold, and wherein the lead connection module comprises a feed-through wire that electrically couples to the external lead. For at least the reasons discussed above with respect to independent claim 1, the rejection of independent claim 9 under 35 U.S.C. § 102(a/e) over Berrang, or, in the alternative, under 35 U.S.C. § 103(a) over Berrang in view of Correas was improper and should be reversed.

Claims 10, 12, 13, and 20 depend from claim 9. For at least this reason, the rejection of claims 10, 12, 13, and 20 was also improper. Appellant respectfully requests reversal of the rejection of claims 9, 10, 12, 13, and 20 under 35 U.S.C. § 102(a/e) over Berrang, or, in the alternative, under 35 U.S.C. § 103(a) over Berrang in view of Correas.

CLAIM 19

Berrang, alone or in view of Correas, fails to disclose or suggest an implantable medical device comprising a control module comprising a hermetic housing, as recited by Appellant's claim 19. The Examiner characterized the elements 18 and 21 as interconnected modules and the ceramic substrate 24 and snap dome 20 as a housing of the element 18 and the ceramic substrate 25 and snap dome 23 as the housing of the element 21.[47] Even if the snap domes 20, 23 and ceramic substrates 24, 25 were housings of modules, an assertion with which Appellant disagrees, Berrang fails to disclose or suggest that the snap domes 20, 23 and ceramic substrates 24, 25, respectively, define a hermetic housing. In fact, Berrang specifically states that the epoxy that is used to coat and encapsulate that covers the components mounted to the ceramic substrates do "not provide a true hermetic or hermetic like seal."[48] For this reason, Berrang provides a single gold coating over the encapsulant surface.[49] Thus, Berrang does not teach or suggest a device including at least two modules comprising separate housings, where a control module housing comprises a hermetic housing, as recited by Appellant's claim 19.

The Examiner asserted that claim 19 was obvious over Berrang. In particular, the Examiner asserted that it would have been an obvious matter of deign choice to modify Berrang such that the electronics 21 were housed in a hermetic housing because Applicant has not

[47] Advisory Action dated June 8, 2009 at page 4, item 7.s
[48] Berrang at column 3, lines 59–65.
[49] *Id.*

disclosed that the individual hermetic seals provides an advantage, is used for a particular purpose, or solves a stated problem.[50] The "obvious matter of design choice" rationale is by itself insufficient to support the rejection of claim 19 under 35 U.S.C. § 103(a).

In order to establish a *prima facie* case of obviousness, the Examiner must still provide a rational reason why one having ordinary skill in the art would have modified Berrang such that the electronics 21 were housed in a hermetic housing.[51] The Examiner has failed to do so. Given the fact that the gold layer of the Berrang device (the "overmold" according to the Examiner) already provides a hermetic housing for the Berrang device, there is no rational reason why one having ordinary skill in the art would have modified Berrang such that the electronics 21 also included a hermetic housing or included a hermetic housing separate from the gold layer.

Even if reliance on the "design choice" rationale to support the rejection of claim 16 can be proper without providing a reason as to why one having ordinary skill in the art would have modified Berrang, the Examiner has failed to properly assert the "obvious matter of design choice" rationale. The Examiner appears to be pulling the "obvious matter of design choice" rationale from legal precedent, which is only permissible if the facts in the prior legal decision are sufficiently similar to those in the application under examination.[52] The "obvious matter of design choice" rationale was used in *In re Kuhle*,[53] which relates to a rearrangement of parts. The Examiner did not use the "obvious matter of design choice" rationale to support an assertion that it would have been obvious to rearrange parts of the Berrang system to arrive at Appellant's claimed invention.

Moreover, even if the "obvious matter of design choice" is relied upon to support an obviousness rejection, the prior art must still provide a motivation or reason for one having ordinary skill in the art to make the necessary changes in a reference device.[54] "The mere fact that a worker in the art could rearrange the parts . . . is not by itself sufficient to support a finding of obviousness."[55] Berrang does not provide any motivation or reason for modifying its device

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[50] Advisory Action dated June 8, 2009 at page 6, item 15.
[51] *KSR*, 550 U.S. 418.
[52] *See* MPEP 2144.04.
[53] *In re Kuhle*, 526 F.2d 533 (CCPA 1975).
[54] *Ex parte Chicago Rawhide Mfg. Co.*, 233 USPQ 351, 353 (BPAI 1984).
[55] *Id.*

such that the electronics 21 are housed in a hermetic housing that is separate from the gold layer (the "overmold" according to the Examiner).

For at least these reasons and the reasons discussed above with respect to independent claim 1, the rejection of claim 19 was erroneous and should be reversed.

REJECTION OF CLAIMS 6, 7, AND 14 UNDER 35 U.S.C. § 103(A) OVER BERRANG IN VIEW OF CORREAS

Claims 6, 7, and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang in view of Correas.

CLAIM 6

Claim 6 depends from independent claim 1 and recites that the lead connection module includes a mechanical lead securing mechanism. Claim 6 is patentable under 35 U.S.C. §§ 102 and 103 for at least the reasons discussed above with respect to claim 1. The Examiner failed to provide support for the rejection of claim 6 under 35 U.S.C. § 103(a) over Berrang in view of Correas. Appellant disagrees with the Examiner's assertion that it would have been obvious to modify the device of Berrang to include a mechanical lead securing mechanism.

As previously discussed, the Examiner characterized the junction 16 of the Berrang device as an external lead. The junction 16 is already secured within the bridge 6 (the "lead connection module" according to the Examiner) of Berrang, and, therefore, there is no need to modify Berrang to include a mechanical lead securing mechanism. In particular, Berrang describes a sealing process used for creating a bond between a substrate and a cable:

> The key components within the housing sections are mounted on an insulated substrate (containing hermetically sealed electrical lead-throughs), where the substrate is comprised of ceramic or glass or a combination thereof, but preferentially ceramic, where the substrate is further bonded to an underlying cable, preferably a ribbon type cable, containing wires, where said ribbon cable is preferably comprised of a bioinert polymer film encapsulating lithographically formed wires. Openings within the polymer film allow electrical connections to be made from said conducting wires to the overlying ceramic substrate lead-throughs. The polymer film is then further bonded to an underlying gold foil substrate. Since some of said components may be comprised of non-biocompatible materials, they require complete hermetic or hermetic like sealing on all surfaces. The preferred embodiment to achieve such all surface sealing is to use a medical grade epoxy to cover said components (mounted onto the ceramic substrate), where said epoxy also provides shape to the overall housing. Alternately, any conformable potting material, such as a bioinert polymer, can be used as an encapsulant

material to cover said components. Since epoxy, or other, encapsulation (over the ceramic substrate) does not provide a true hermetic or hermetic like seal, said encapsulant surface is coated first, preferably, with a thin coating of vacuum deposited gold, or alternately, with an electroless gold deposition, where such a first coating of gold is subsequently thickened by an electro deposition of gold. Alternate embodiments include coating the electro deposited gold layer with titanium (or platinum), and/or with medical grade silicone.[56]

Berrang further states that "[t]he same gold coating processes are also used to provide a gold seal between the bridge connecting the two housing sections, and the point at which the connectors from the microphone and electrode array enter the housing bridge [i.e., the junction]."[57] Thus, the junction of the Berrang device is already secured to the bridge via a bonding mechanism. Berrang fails to disclose or suggest that the bonding mechanism is inadequate in any manner for securing the junction to the bridge. A person of ordinary skill at the time of the invention would have had no rational reason to modify Berrang to include a mechanical lead securing mechanism, as recited by claim 6, additionally or alternatively to the bonding mechanism already incorporated by Berrang. Thus, the rejection of claim 6 under 35 U.S.C. § 35 U.S.C. § 103(a) over Berrang in view of Correas was improper and should be reversed.

CLAIM 7

Claim 7 depends from dependent claim 6 and recites that the mechanical lead securing mechanism (of claim 6) comprises a tool-less mechanical lead securing mechanism. Claim 7 is patentable under 35 U.S.C. §§ 102 and 103 for at least the reasons discussed above with respect to claims 1 and 6. Claim 7 also recite additional features that are neither disclosed nor suggested by the cited art.

In support of the rejection of claim 7 under 35 U.S.C. § 103(a) over Berrang in view of Correas, the Examiner stated that "Berrang discloses the essential features of the claimed invention except for . . . [a] tool-less mechanical connection"[58] and that "Correas teaches . . .

[56] Berrang at column 3, lines 38–67.
[57] *Id.* at column 3, line 67 – column 4, line 4.
[58] Advisory Action dated June 8, 2009 at page 6.

provid[ing] tool-less lead securing (Figs. 5 and 6) to provide the predictable result of a simple implantation that requires few implantation implements."[59] The Examiner's assertion of obviousness lacks a rational underpinning, and, therefore, is insufficient to render Appellant's claim 7 obvious.[60]

Berrang fails to disclose or suggest that implantation of the cochlear prosthesis device is complicated in any manner or that implantation requires more than a few implantation implements. In fact, Berrang states that "the implant is designed to reduce the surgical complexity and time needed by the surgeon for device implantation."[61] Because the bridge and junction of Berrang are not separable, implantation of the Berrang device is not necessarily any more complicated than implantation of the Correas device and does not necessarily require any more implantation implements than implantation of the Correas device. As a result, the proposed rationale for modifying Berrang in view of Correas in the manner proposed by the Examiner lacks a rational underpinning.

Additionally, as discussed with respect to claim 6, a person of ordinary skill at the time of the invention would have had no rational reason to modify the device of Berrang to include an additional or alternative securing mechanism; thus, a person of ordinary skill at the time of the invention would have had no rational reason to modify the device of Berrang to include a mechanical lead securing mechanism, much less a tool-less mechanical lead securing mechanism. For at least these reasons, the rejection of claim 7 under 35 U.S.C. § 103(a) over Berrang in view of Correas was improper and should be reversed.

CLAIM 14

Claim 14 depends from independent claim 9 and recites that the lead connection module (of claim 9) is configured to receive an iso-diametric external lead. Claim 14 is patentable under 35 U.S.C. § 103(a) for at least the reasons discussed above with respect to claim 9. Appellant respectfully requests reversal of the rejection of claim 14.

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[59] *Id.* at page 6–7.
[60] *See KSR*, 550 U.S. at 418.
[61] Berrang at column 2, lines 36–38.

SUMMARY

The Examiner has failed to meet the burden of establishing a *prima facie* case of nonpatentability with respect to claims 1–10, 12–15, and 19–21. In view of Appellant's arguments, the final rejection of claims 1–10, 12–15, and 19–21 was improper and should be reversed, and all of the pending claims should be allowed. Appellant respectfully requests separate review by the Board for each of the grounds of rejections addressed above under separate headings.

Date: September 14, 2009

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CLAIMS APPENDIX

Claim 1: An implantable medical device comprising:

at least two interconnected modules, each of the modules comprising a respective one of at least two housings to house the respective modules; and

an overmold that at least partially encapsulates each of the housings and is at least partially flexible to allow relative motion between the modules, the overmold comprising a lead connection module configured to accept an external lead, wherein the external lead is separable from the lead connection module and wherein the lead connection module comprises a feed-through wire that electrically couples to the external lead.

Claim 2: The implantable medical device of claim 1, wherein at least one module comprises a control module containing electronic components.

Claim 3: The implantable medical device of claim 1, wherein the overmold comprises a first material and a second material, and the lead connection module is embedded within the first material.

Claim 4: The implantable medical device of claim 3, wherein the first material comprises a non-elastomeric material.

Claim 5: The implantable medical device of claim 1, wherein the feed-through wire electrically couples the external lead to an electronic component within the implantable medical device.

Claim 6: The implantable medical device of claim 1, wherein the lead connection module includes a mechanical lead securing mechanism.

Claim 7: The implantable medical device of claim 6, wherein the mechanical lead securing mechanism comprises a tool-less mechanical lead securing mechanism.

Claim 8: The implantable medical device of claim 1, wherein the implantable medical device has a maximum thickness of between approximately 4 millimeters and approximately 8 millimeters.

Claim 9: An overmold for a modular implantable medical device that includes a plurality of modules, each of the modules comprising a respective housing to house the respective module, the overmold comprising:

a first material configured to hold at least part of the housing of one of the modules;

a second material coupled to the first material, wherein at least one of the first or second materials is at least partially flexible to allow relative motion between the modules; and

a lead connection module configured to accept an external lead, wherein the external lead is separable from the lead connection module, the lead connection module being embedded within the overmold, and wherein the lead connection module comprises a feed-through wire that electrically couples to the external lead.

Claim 10: The overmold of claim 9, wherein the first material comprises a non-elastomeric material.

Claim 12: The overmold of claim 9, wherein the second material comprises silicone.

Claim 13: The overmold of claim 9, wherein the lead connection module is embedded within the first material.

Claim 14: The overmold of claim 9, wherein the lead connection module is configured to receive an iso-diametric external lead.

Claim 15: The implantable medical device of claim 1, wherein the housings are horizontally distributed at respective locations of the overmold, and separately encapsulated by the overmold.

Claim 19: The implantable medical device of claim 2, wherein the housing of the control module is hermetic.

Claim 20: The overmold of claim 9, wherein at least one of the respective housings is hermetic.

Claim 21: The implantable medical device of claim 1, wherein the overmold partially encapsulates each of the housings.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE